No. 73020-2

**SUPREME COURT OF THE STATE OF WASHINGTON**

WASHINGTON EMPLOYERS CONCERNED ABOUT REGULATING ERGONOMICS, et al.,

Appellants,

v.

DEPARTMENT OF LABOR & INDUSTRIES, et al.,

Respondents.

# BRIEF OF APPELLANT


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## I. INTRODUCTION

This is an appeal challenging the Department of Labor and Industries' (hereinafter "DLI" or "Department") promulgation of WAC 296-62-051 et seq. ("the Ergonomics Rule" or "the Rule"), allegedly aimed at reducing what the Department calls "work-related musculoskeletal disorders" ("WMSDs"). This appeal does not present the broader issue of whether ergonomic principles may improve the workplace or enhance employee comfort. Rather, Appellants Washington Employers Concerned About Regulating Ergonomics ("WE CARE"), et al., challenge the specific Rule promulgated in May 2000. That single "ergonomics" rule purports to regulate the infinite variety of human activity in the workplace and dozens of "disorders" allegedly associated with physical activity. It is no surprise that DLI fails at this impossible regulatory objective. DLI must advance sufficient scientific evidence to show that the regulated work activity causes definable disorders, medical evidence to show that its Rule will have a positive effect on those disorders, and economic evidence to show that benefits will exceed costs that even DLI acknowledges to be "significant." AR 118029.[1] Whether

[1] Citations to the Clerk's Papers ("CP") are provided throughout the brief where available. However, the exhibits designated by WE CARE were not assigned CP numbers. Accordingly, WE CARE will refer to exhibits from the official rule-making file the way it did below, by Administrative Record ("AR") number. These numbers correspond with the Bates stamp number, assigned by DLI upon production of the documents, beginning either "L&I Docs # ___" or "PCH # __." As for the additional documents admitted into the record by the Superior Court below, WE CARE will refer to

(continued...)

or not DLI could meet this daunting burden for some rule regulating ergonomics, it has not met these legislatively mandated requirements for this Rule.

## II. ASSIGNMENTS OF ERROR

1. DLI erred when it acted outside its authority to promulgate the Ergonomics Rule.

2. DLI erred when it failed to make its complete or substantially complete cost benefit analysis available to the public prior to the close of public hearings and before adoption of the Rule.

3. DLI erred in failing to include OSHA's Preliminary Economic Analysis ("PEA") and related documents in the official rule-making file or to otherwise make them available to the public when DLI relied heavily on the PEA in calculating the Rule's costs and benefits.

4. DLI erred in calculating the Rule's costs and benefits.

5. DLI erred in concluding that the Ergonomics Rule is "needed" to achieve the goals of RCW 49.17.

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(...continued)
them by Bates stamp number beginning "WC #__," assigned by DLI upon production of the documents, or where no such Bates number exists, by Exhibit number assigned by WE CARE below and in Appendix 2, attached. All documents in the Administrative Record to which WE CARE cites, are indexed, marked by Exhibit number, and attached as Appendix 2 hereto.

6. DLI erred in finding that epidemiological studies were "the best available evidence" when contradictory randomized controlled studies existed and no dose response curve had been established.

7. DLI erred in finding that the Ergonomics Rule is "the least burdensome alternative" for achieving the goals of RCW 49.17.

8. DLI erred when it failed to coordinate the Rule with other laws "applicable to the same activity or subject matter."

9. DLI erred in promulgating a rule that is unconstitutionally vague.

10. The Superior Court erred when it refused to supplement the record pursuant to RCW 34.05.562.

## III. ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

1. Is an agency's adoption of a significant legislative rule governed by the specific standard set out in RCW 34.05.328(2), which requires an agency to justify requisite determinations with evidence of a sufficient quantity and quality that would persuade a reasonable person, or is it governed by the more general arbitrary and capricious standard set out in RCW 34.05.570(2)(c), when the Legislature expressly provided that the more general standard controls "except to the extent that this chapter or another statute provides otherwise"? (Assignments of Error 1 through 8.)

2. Must an agency make a substantially complete cost benefit analysis under RCW 34.05.328(1) and related materials available to the public prior to the close of public hearings and in advance of adopting a

significant legislative rule to ensure meaningful public participation in the rulemaking process? (Assignments of Error 2, 3 and 4.)

3. Does DLI have the authority under WISHA to regulate simple physical activity even though it does not constitute a "toxic material" or "harmful physical agent" under RCW 49.17.050(4)? (Assignments of Error 1, 6 and 7.)

4. Can epidemiological studies which reflect only correlations constitute the "best available evidence" under RCW 49.17.050(4) when contradictory randomized controlled studies which demonstrate causation are available and no dose response curve has been established? (Assignments of Error 5, 6 and 7.)

5. Did DLI satisfy the requirements of RCW 34.05.328(1)(b) and (d) in finding that the Rule was "needed" and, after considering other options, that it is "the least burdensome alternative"? (Assignments of Error 1, 4, 5, 6, 7, and 8.)

6. Did DLI adequately coordinate the Rule, which regulates physical activity in the workplace, with other state and federal laws applicable to the same activity or subject matter as required by RCW 34.05.328(1)(h) when it failed to address state disability or workers compensation laws? (Assignment of Error 8.)

7. Is the Ergonomics Rule consistent with constitutional due process requirements, when it purports to address conditions that are not defined, and its compliance requirements are so uncertain that persons of ordinary

intelligence cannot be sure what actions are required and what are not? (Assignment of Error No. 9.)

8. Should the record on review be supplemented, when the offered evidence relates to the agency action at the time it was taken and is needed to decide disputed facts in a rule making? (Assignment of Error 10.)

## IV. STATEMENT OF THE CASE

### A. Introduction.

Under the Washington Industrial Safety and Health Act, RCW 49.17 ("WISHA"), DLI has the authority to promulgate standards regulating health hazards arising from "gases, vapors, dust, or other airborne particles, toxic materials, or harmful physical agents." RCW 49.17.050(4). Citing this authority, AR116743 (DLI's Preproposal Statement of Inquiry), DLI promulgated the Rule at issue here, WAC 296-62-051, et seq., on May 25, 2000. See Respondent's Answer to Statement of Grounds at 1. The express purpose of the Rule was to reduce WMSDs. See CES, AR 117631.

Subsequent to adoption of the Rule but prior to its implementation, WE CARE filed a Petition for Review in the Thurston County Superior Court. That court denied WE CARE's petition. On the issue of authority under RCW 49.17.050(4)'s "harmful physical agent" provision, the court stated that it was "not sure who is correct about the meaning" of this term, but found sufficient alternative authority under RCW 49.17.010 (general statement of legislative purpose) and RCW 49.17.010 (establishing

rulemaking procedures) to support DLI's action. CP 2172-2173 (Order Denying Petition for Review). The court also found that RCW 34.05.328(1)'s requirement of a cost-benefit analysis and implementation plan "[b]efore adopting the rule" does not mandate issuance of these documents prior to the date of promulgation, id. at CP 2170-2172; that in light of the "large margin of error" in DLI's cost-benefit analysis, the errors in that cost-benefit analysis did not render it "arbitrary and capricious," id. at CP 2177-2180; and that DLI could base its scientific case on correlations from epidemiological evidence notwithstanding contrary randomized controlled trials and the general recognition that these studies were superior in quality.

WE CARE continues its challenge to the Rule.

**B. The Rule's Requirements.**

The Rule at issue seeks to regulate WMSDs defined as "work-related disorders that involve soft tissues such as muscles, tendons, ligaments, joints, blood vessels and nerves." WAC 296-62-05150. WMSDs do not include "injuries from slips, trips, falls, motor vehicle accidents or being struck by or caught in objects," id., but the nature and scope of "disorders" outside these exceptions is not further defined. The Rule proposes to reduce WMSDs within Washington through "ergonomics" generally defined as the art of adapting the work environment to the comfort of the human body.

To this end, every Washington public and private employer must first determine if it has any "caution zone jobs." WAC 296-62-05103. A

caution zone job is any job in which an employee's typical work activities include any of the fourteen specified physical "risk factors"– various motions, postures and physical activities that the Department feels give rise to a risk of various physical ailments. WAC 296-62-05105. These "caution zones" include such activities as repeating a motion continuously for more than two hours in a workday, lifting a 75 pound object at any time during a workday, or lifting more than 10 pounds at least twice per minute for two hours. Id.

If an employer identifies caution zone jobs, it must then determine whether these jobs have WMSD "hazards." See WAC 296-62-05130. Generally, the Rule declares that a "hazard" exists if the employee must engage in the "risk factor" for longer than a specified threshold duration that varies from risk factor to risk factor. See id. These "hazards" include repeating a motion continuously for six hours per day without significant wrist flex or hand force, repeating a motion continuously for only two hours if wrist flex and hand force is involved, and lifting weight in excess of calculations on a chart that may or may not be less restrictive than the "caution zone" threshold. See WAC 296-62-05174. Alternative hazard thresholds may be used but these must be "at least as effective" as similar quantitative calculations. WAC 296-62-05130. Identification of "hazards" under the Rule does not take into account whether any employee in that workplace has ever suffered a WMSD. See id.

Once "hazards" have been identified, the Rule requires employers to reduce these work activities through physical changes to the workplace

("engineering controls") and work practices ("administrative controls"). See WAC 296-62-05130. Subject employers are also required to provide ergonomic awareness education to employees and annually review their ergonomic compliance and efforts. See WAC 296-62-05120; WAC 296-62-05140(3). Non-complying employers will be subject to civil and criminal penalties. See RCW 49.17.180 and RCW 49.17.490.

According to the Rule's implementation schedule, employers must comply with the Rule's requirements on a staggered basis, depending upon the industry and size of the employer. See WAC 296-62-05160. The first applicable deadline for employers with 50 or more employees in selected industries was July 1, 2002. Id. Although the Governor subsequently stayed enforcement of the Rule by temporarily forbidding the issuance of fines and citations, employers are still required to comply with the Rule's substantive requirements by the specified dates.

**C. Procedural Rule-Making Requirements Under the APA and the RRA.**

Anytime an agency such as DLI promulgates a rule like the one at issue here, it must comply with the procedural rule-making requirements of the APA. When the rule is a "significant legislative rule" (as DLI admits the Ergonomics Rule is), the agency must comply with additional procedural requirements recently mandated by the Regulatory Reform Act of 1995, RCW 34.05.328 ("RRA"). See AR 118030-34 (wherein DLI recognizes that the Ergonomics Rule is a significant legislative rule). The Legislature's express intent in adopting the RRA was to grant "[m]embers

of the public affected by administrative rules...the opportunity for a meaningful role in their development." 1995 Laws ch. 402, sec. 2(d).

Thus, prior to adopting the Rule, DLI was required under the APA to give proper notice of and hold a public hearing soliciting the public's recommendations, suggestions or changes to the proposed rule. See RCW 49.17.040, RCW 34.05.320. This entailed publishing a notice in the state register, including a copy of the small business economic impact statement ("SBEIS") prepared under RCW 19.85 and indicating whether RCW 34.05.328 governing significant legislative rules applied. See RCW 34.05.320(1)(k) and (l). The Department was further responsible for making a good faith effort to insure that the information provided on the proposed rule was accurate, to accept timely submitted comments and supporting data, and to provide opportunity for oral comment at the public rule-making hearings. See RCW 34.05.325.

Thereafter, DLI was required to prepare a concise explanatory statement ("CES") identifying the reasons for the rule, describing any differences between the final and proposed rule, summarizing all comments received, and explaining how and why the final rule reflects or does not reflect the agency's consideration of the merits of those comments. See id. Throughout this process, DLI was required to maintain an official rule-making file. The file, along with any materials incorporated therein by reference, was required to have been made available by DLI for public inspection. See RCW 34.05.370.

Because the Ergonomics Rule is a significant legislative rule, the RRA further required DLI to: (1) state the general goals and specific objectives of the statute implemented by the rule; (2) determine that the rule is needed to achieve these goals and objectives and analyze alternatives to rule-making and the consequences of not adopting a rule; (3) determine that the benefits of the rule outweigh its costs; (4) after considering alternative versions of the rule, determine that the rule is the least burdensome alternative to achieve the identified goals and objectives; (5) determine that the rule does not require the violation of some other state or federal law; (6) determine that private entities are not more adversely affected than public entities; (7) determine that any variances from federal law applicable to the same activity or subject matter are justified; and (8) coordinate the rule to the maximum extent practicable with other laws applicable to the same activity or subject matter. See RCW 34.05.328(1)(a)-(h). The RRA is express: the agency is required to make these determinations before adopting the regulation. The RRA specifically requires that these determinations be based on evidence "of sufficient quantity and quality so as to persuade a reasonable person that the determinations are justified." RCW 34.05.328(2).

In addition, before adopting the rule, DLI was required to file a rule implementation plan pursuant to the RRA, describing how the agency will: 1) implement and enforce the rule, including the resources to be used; 2) inform and educate affected persons about the rule; 3) promote and assist voluntary compliance; and 4) evaluate whether the rule achieves

the purpose for which it was adopted, including identification of interim milestones to assess progress and objectively measurable outcomes. See RCW 34.05.328(3).

Finally, after promulgating a rule which regulates the "same activity or subject matter" as another provision of federal or state law, the RRA requires that DLI: 1) provide a list of those federal and state laws to the business assistance center; and 2) coordinate the implementation and enforcement of the rule with the other federal and state entities regulating such other laws by deferring to the other entity, designating a lead agency, or entering into an agreement that specifies how coordination will occur. See RCW 34.04.328(4).

**D. Federal Overlay: OSHA's Ergonomics Rule.**

At the same time DLI was promulgating its Rule, the federal Occupational Safety and Health Administration ("OSHA") was promulgating an ergonomics rule of its own. Unlike the Rule at issue here, the federal rule was triggered only when there was a reported injury. See 65 Fed. Reg. 65548-49 (2000). However, like the Washington rule, OSHA's rule relied upon engineering and administrative controls as a means of reducing musculoskeletal disorders. See 29 C.F.R. § 1910.919(b) (proposed), 64 Fed. Reg. 66071.

In completing its cost-benefit analysis for Washington's Rule, DLI relied heavily upon OSHA's preliminary cost estimates for the federal rule proposed in November 1999. See CBA, AR 118042-43 (referring to OSHA's Preliminary Economic Analysis ("PEA"), OSHA Docket S-777,

Exh. 28-1). Ultimately, in March of 2001, Congress set aside OSHA's ergonomics rule, finding that it was "unduly burdensome and overly broad" and failed to strike an appropriate balance between high costs and "uncertain benefits." See PL 107-5 (2001); Signing Statement of the President, March 21, 2001.

For purposes of industrial safety and health, Washington state is required to adopt standards which equal or exceed those standards prescribed by OSHA. See RCW 49.17.010; RCW 49.17.050(2). Thus, because OSHA did not ultimately enact a federal standard on ergonomics, Washington's Ergonomics Rule exceeds federal law (and all other state laws[2]) in this area.

**E. Efforts to Supplement the Record on Review.**

Prior to the hearing on the merits below, WE CARE moved the Superior Court for the admission of additional evidence to supplement the "official rule-making file" kept by DLI pursuant to RCW 34.05.370. See CP 88-100 (Motion for Preliminary Ruling on Admission of Documents). While the APA generally limits judicial review to the agency record (ie. the "official rule-making file"), it expressly provides that the record "may be supplemented by additional evidence taken pursuant to this chapter."

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[2] California has a standard governing "repetitive motion injuries"—a subset of WMSDs—but it applies only when there have been at least two objectively diagnosed injuries in a single job, process, or operation within 12 months , and it does not set any quantitative thresholds for "hazards" or required "controls." Cal. Code of Regulations, Tit.8, § 5110.

RCW 34.05.558. That section specifically allows for the admission of additional evidence where it goes to the validity of the agency's action at the time it was taken and is necessary to decide several different types of disputed issues identified in the statute. See RCW 34.05.562(1). The claims that support the admission of additional evidence include: 1) "[u]nlawfulness of procedure or of decision-making process, and 2) "[m]aterial facts in rule-making, brief adjudications, or other proceedings not required to be determined on the agency record." Id.

The Superior Court granted WE CARE's motion in part and denied it in part. See CP 507-512 (Order). While the court admitted OSHA's PEA, it denied the admission of documents relating to the PEA which undermine the PEA's integrity. Id. Likewise, the court admitted multiple medical studies relied upon or referenced by DLI in the official record, but refused to admit a later study that sheds light on the validity of the Rule at the time it was adopted. Id. Finally, the Superior Court admitted DLI's working notes. However, correspondence from DLI to various Washington employers or prospective employers reflecting DLI's administration and enforcement of the Rule, bearing on the validity of DLI's Rule implementation plan at the time it was promulgated, were rejected, along with other reports and correspondence. Id.

## V. ARGUMENT

### A. As a "Significant Legislative Rule," the Ergonomics Rule Must be Evaluated by Standards Different Than Those Previously Enunciated by the Washington Courts.

The standards by which this Court previously reviewed administrative actions were changed by the RRA for "significant legislative rules." The RRA mandates that an agency comply with additional procedures, beyond those previously established by the APA in promulgating rules. The RRA also adopted a standard of review for such rules which is substantially less deferential to agency action and interpretation.

Under the RRA, an agency must make enumerated determinations, not previously required by the APA. See RCW 34.05.328(1). The RRA specifically requires that these determinations be based on evidence "of sufficient quantity and quality so as to persuade a reasonable person that the determinations are justified." RCW 34.05.328(2). Thus, "significant legislative rules" are subject to higher scrutiny than are other rule makings under the Administrative Procedure Act. Compare Neah Bay Chamber of Commerce v. Dep't of Fisheries, 119 Wn.2d 464, 470, 832 P.2d 1310 (1992)(under earlier formulation, "arbitrary and capricious" standard represents middle level of review). Any suggestion that significant legislative rules remain subject to the "arbitrary and capricious" standard of review established in RCW 34.05.570(2)(c) is belied by the language of the APA itself. The Legislature has specifically determined that the APA's judicial review provisions in RCW 34.05.570 apply "except to the

extent that this chapter or another statute provides otherwise." RCW 34.05.570(1). In the instance of significant legislative rules, the Legislature has required that the determinations called for by RCW 34.05.328(1) be supported by evidence that would "persuade a reasonable person." RCW 34.05.328(2). The Legislature could not have more clearly rejected the notion that such rules must be upheld if they could "conceivably be the product of a rational decision-maker." Neah Bay, 119 Wn.2d at 473. Accordingly, the Court must review, under a reasonable person test, the sufficiency of the Department's findings on the subjects mandated by RCW 34.05.328(1)(b) through (g).

This heightened review for the determinations required by RCW 34.05.328(1)(b) through (g) is, indeed, a substantial change. It is a change, moreover, that this Court has not previously reviewed. Indeed, even the Court's decision earlier this year in Rios v. DLI, 145 Wn.2d 483, 39 P.3d 961 (2002), is not of assistance. While the Rios court did strike down some of DLI's actions, none of those actions involved the enactment of "significant legislative rules" under the RRA.

In interpreting this aspect of the RRA for the first time, the Court should reject any interpretation that would give this provision only superfluous effect. For example, DLI (or other state rule-issuing agencies) might argue that RCW 34.05.328(2) calls only for *the agency* to make the determination that its rule is supported by evidence sufficient to convince a reasonable person, and this determination is not for a reviewing court. Although the legislature is presumed not to engage in meaningless acts,

any interpretation of the statute that precludes enforcement achieves just that result. See W. Washington Cement Masons Health & Sec. Trust Funds v. Hillis Homes, Inc., 26 Wn. App. 224, 232, 612 P.2d 436, 441 (1980). A statutory interpretation that renders the statute unenforceable is to be avoided. See Kirk v. City of Kennewick, 99 Wn.2d 832, 836, 664 P.2d 1240, 1242 (1983). Any argument that the reviewing court may not review whether the RRA's new requirements are supported by evidence satisfying the reasonable person test achieves only that unacceptable result.

Thus, at a certain level, the debate whether RCW 34.05.328(2) establishes a new standard of review for significant legislative rules is academic. Whether or not that subsection establishes a standard of review, it is clearly a "statutory rulemaking procedure." Under the APA, if a rule is adopted "without compliance with statutory rulemaking procedures," it is invalid. RCW 34.05.570(c); Failor's Pharmacy v. DSHS, 125 Wn.2d 488, 497, 886 P.2d 147 (1994). Therefore, if the determinations required by RCW 34.05.328(1)(b) through (g) are not supported by evidence of sufficient quantity and quality so as to persuade a reasonable person that the determination is justified, DLI has failed to comply with statutory rulemaking procedures. In that event, the Ergonomics Rule must be set aside.

**B. The Department Violated the Regulatory Reform Act of 1995 by Not Adopting or Publishing a Cost Benefit Analysis Prior to Adoption of the Rule.**

The RRA is explicit: those agencies required to go through the additional steps for a "significant legislative rule" must do so before the adoption of the rule. See RCW 34.05.328(1). The Department failed to do so. By failing to comply with the RRA, DLI deprived the public of a meaningful ability to participate in the development of this far-reaching rule.

It is for this reason that the Court must not look tolerantly on the Department's failings in this regard as some mere technical violation. In the RRA, the Legislature recognized that while regulatory actions are necessary, they also have the capacity "to discredit government, make[ ] enforcement of essential regulations more difficult, and detrimentally affect[ ] the economy of the state and the well-being of our citizens." 1995 Laws, ch. 403, Sec. 1(1)(a). Thus, the Legislature intended to insure that members of the public affected by new rules "must have the opportunity for a meaningful role in their development." Id. at Sec. 1(2)(d).

Rulemaking in the "sunshine" has always been at the core of the legislature's concern. Thus, Washington's APA has long required that the public be allowed to comment on the regulations that will govern them, including the data underlying those regulations. See RCW 34.05.325. Thus, our courts have recognized that "the purpose" of the APA's rulemaking procedures is to "ensure that members of the public can

participate meaningfully in the development" of such rules. Hillis v. Dep't of Ecology, 131 Wn.2d 373, 399, 932 P.2d 139 (1997) (emphasis added).

Quite simply, in enacting the RRA the Legislature required agencies to do more before enacting significant legislative rules. If the Legislature's express direction – that agencies develop a cost-benefit analysis, and do so before adopting a significant legislative rule – is to be given effect, then those determinations must be made sufficiently before the rule's adoption for the public to comment.

That was precisely the conclusion of the only other body known to Appellants to have reviewed a significant legislative rule since the adoption of the RRA. In Association of Washington Business v. Department of Ecology, the Shorelines Hearing Board reviewed an agency's new rule under the RRA. SHB No. 00-037 (August 27, 2001) (attached as Exhibit 1). The Board invalidated the new regulation expressly because the Department's cost benefit analysis and implementation plans were not completed until after the period for public comment had closed. Id. at p. 18.

Any contrary result – such as upholding the preparation of the determinations required by the RRA when completed contemporaneously with the adoption of the rule – would eviscerate the public's right to meaningful participation in the rulemaking process. Such a result, flouting the Legislature's express intent, should not be countenanced.

DLI was clearly aware of its duty to perform a cost benefit analysis prior to adopting the Rule. In a supplement to its CR-102 packet filed in November 1999, the Department noted that it "had not yet conducted the formal benefit-cost analysis required for publication of a new significant legislative rule." AR 102745. Yet, the Department did not publish its cost-benefit analysis until the release of the Concise Explanatory Statement in conjunction with the Department's adoption of the Ergonomics Rule on May 25, 2000, three months after the period for public comment had closed on February 24, 2000.[3] See AR 102943; 106176. By only publishing its cost-benefit analysis after the closure of the public comment period, the Department deprived Washington citizens of their statutory right to meaningfully participate in the agency's rule making process and shielded its flawed analysis from public scrutiny during the only time when such scrutiny could have any impact: before the adoption of the Rule. See Hillis, 131 Wn.2d at 399.

Any objection by DLI that the requirement to publish the cost benefit analysis meaningfully before rule adoption would be inconvenient simply should not be heard. When the Legislature specifies a procedure

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[3] To the extent the Department may attempt to rely on its publication of the SBEIS to satisfy the requirements of RCW 34.05.328(1)(c), such an argument must fail. Preparation of a SBEIS is a separate statutory prerequisite to rulemaking required by the Regulatory Fairness Act, RCW 19.85. While the Department has attempted to characterize the SBEIS as a reflection of its "preliminary" cost-benefit analysis, the Department has also admitted that the SBEIS "[wa]s not a cost-benefit analysis." AR 102783; CES, AR 117815.

for the agency to follow, it must comply. See WITA v. WUTC, 110 Wn. App. 498, 41 P.3d 1212 (2002). The RRA is not a technicality to be evaded; it is an attempt to ensure meaningful public participation in the development of significant legislative rules -- governmental actions that can impose burdens as onerous as any statute or ordinance. DLI's flouting of the RRA's requirements cannot be condoned.

The Department failed to comply with the express requirements of the RRA, RCW 34.05.328(1), and the ordinary remedy for failure to comply with the rule-making requirements of the APA is invalidation of the resulting illegal regulation. See, e.g., Hillis, 131 Wn.2d at 400; Failor's Pharmacy v. DSHS, 125 Wn.2d 488, 497, 886 P.2d 147 (1994). Indeed, RCW 34.05.570(2)(c), expressly provides for invalidation of a rule where, as here, it was "adopted without compliance with statutory rule-making procedures." Id.

**C. DLI's Cost-Benefit Analysis was Substantively Faulty and Lacked the Requisite Evidentiary Support.**

The RRA requires that before adopting a significant legislative rule, an agency must "determine that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented." RCW 34.05.328(1)(c). At the hearing below, DLI acknowledged that the RRA requires *it* to justify this determination with evidence of a sufficient quantity and quality to persuade a reasonable person. See RCW 34.05.328(2); Report of Proceedings ("RP") 129:8-15.

Yet, erroneously applying a less stringent standard, the court found that the evidence was "of sufficient quantity and quality to…conclude that the Department was not arbitrary and capricious." CP 2180.

The Superior Court acknowledged a lack of "certainty" in the numbers in light of the problems noted by WE CARE, but it was also persuaded by the "large margin of error" left by the 4 to 1 ratio between DLI's $80 million cost estimate and its claim of $340 million in annual benefits. Id. It is not WE CARE's burden, however, to show that DLI's estimates exceeded a "margin of error" created by exaggerated benefit claims and underestimated costs. Nor is it sufficient to effectively declare the analysis "close enough for government work." Perlman v. Zell, 185 F.3d 850, 858 (7th Cir. 1999). See also CP 606. If the methodology that yielded DLI's calculations was flawed in important respects, then the analysis cannot persuade a "reasonable person" under any standard of review. For the reasons demonstrated herein, DLI's cost-benefit analysis cannot pass this test.

**1. Costs were greatly underestimated.**

In estimating the probable costs of the Rule, DLI primarily focused on two factors: 1) the number of jobs likely to be affected by the Rule; and 2) the cost of controls mandated by the Rule for each of those affected jobs. See CBA, AR 118033-34. Multiplying these two factors, DLI arrived at its cost estimate. See id. However, because the data used by DLI to calculate each of these primary factors was faulty, as discussed below, the ultimate cost estimate was well below that which it should have

been. The evidence, therefore, cannot persuade a reasonable person that DLI's determination of costs was justified.

**a) The number of jobs affected by the Rule was substantially underestimated by DLI.**

According to the CBA, DLI relied on data collected from a 1998 department survey to estimate the number of jobs affected by the Rule. See CBA, AR 118036-37. The survey asked employers how many employees performed certain physical movements and from that extrapolated the number of jobs affected. See Employer Questionnaire, AR 118104. However, the movements did not correspond to the risk factors later targeted by the Rule. For example, the survey inquired about lifting ten pounds more than once per minute while the Rule regulates lifting ten pounds twice per minute for more than two hours in the day. Compare AR 118104 with WAC 296-62-05105. Likewise, the survey inquired about carrying heavy loads (30+ pounds) over seven or more feet while the Rule regulates carrying more than 25 pounds over the shoulders, below the knees, or at arm's length more than 25 times per day. See id. Accordingly, the data collected from the survey and relied upon by DLI reflected some other set of variables, not the risk factors actually regulated by the Rule.

The "hazard" thresholds purportedly tested by the survey lie at the very heart of the Rule. As explained below, these thresholds are burdensome, overly restrictive, and lacking in scientific support. They are anything but freely interchangeable. By asking about different activities

that are likely to be less common in Washington workplaces than the actual "hazards" regulated in the Rule, the survey substantially underestimates the impact of these thresholds on Washington employers.

Indeed, several of the risk factors regulated by the Rule were not even covered by the survey. For example, risk factors arising from the position of the neck, the posture of the back, and the angle of the knees (squatting and kneeling) were not so much as mentioned in the survey.[4] Compare WAC 296-62-05105 with CBA, AR 118104. This means that entire categories of jobs that implicate these risk factors were not included in DLI's calculation of the total number of jobs affected by the Rule, lowering that number significantly and any cost estimate derived from it.

The survey also assumed that hazards would not exist, and thus control measures would not be required, absent four or more hours of exposure each day. See CBA, AR 118037. By contrast, the Rule deems many activities "hazards" after much less than four hours of exposure and sometimes based on only one movement per day.[5] See WAC 296-62-05174. Therefore, DLI's calculation based on this survey data left out

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[4] Rather, the survey only inquired as to "work[ing] with hands about shoulder level." CBA, AR 118104.

[5] For example, multiple activities of the arms, wrist, hands, neck, shoulders, and elbows can create a correctable hazard after two to three hours of exposure according to the Rule. See WAC 296-62-05174, App. B at B-3 and 4. Lifting performed more than ten times per minute for two hours is prohibited by the Rule if the weight of the object being lifted is above ten pounds. See id at B-5. Pursuant to the vibration table, use of certain power tools for only a few minutes can constitute a hazard under the Rule. See id. at B-6. Finally, lifts of as little as thirty pounds performed once per day may be forbidden depending upon posture. See id. at B-5.

another entire segment of jobs which will be affected by the Rule due to hazards occurring at less than the four hour exposure mark measured and accounted for by the survey.

Finally, the fact that DLI even relies on the results of the 1998 survey at all is troubling given the low response rate. DLI randomly selected 10,000 employers as the original sample for the survey. See CBA, AR 118036-37. Of those, only 6,540 were successfully contacted and only 4,906 provided responses. See id. The participation rate based on the original sample, therefore, was 49%.[6] DLI did not even take this low response rate into account, yet, it dismissed an award-winning medical study at Boeing that conflicted with its view of the science for that very reason. See CES, AR 117653.[7] Coupled with the survey's sparse coverage of specific industry groups, the low response rate raises serious questions about DLI's data collection techniques and the quality of the resulting data. See CBA, AR 118122.

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[6] The response rate for small business was even lower: less than 45%. See WC 046108, DLI's Working Notes (App. Designation CP, Exh. MMM).

[7] There, DLI found a 40.5% participation rate based on the original sample to be "low" and a "serious limitation" to the study. Id. In an apparent effort to improve perception of its survey, however, DLI characterized the survey's participation rate as the percentage of employers who responded from the subset of employers "successfully contacted" rather than from the original sample. See CBA, AR 118037-38. Even using this more lenient standard, the participation rate was poor at 75%. See id. A second study by the Department had an even lower participation rate.: from an original sample of 5,644, of which 4,425 were successfully contacted, only 1,085 responded. See CBA, AR 118037-38. Thus, the participation rate using the original sample was 19.2% while DLI's standard for measuring participation rendered a 24.5% rate. See id.

b) **DLI severely underestimated the cost of controls per job.**

DLI readily admits that it did not calculate the cost of specific controls required by its Ergonomics Rule. See CBA, AR 118042-43. Rather, DLI relied on the 1999 PEA prepared by OSHA for the then-proposed federal ergonomics rule. See id.; PEA, CP 102-107. As mentioned above, the proposed federal rule took a very different approach than Washington's rule to regulating ergonomics. For example, the proposed federal standard required employers to "eliminate or materially reduce the MSD hazards," offering an "incremental abatement process" in which controls could be attempted in stages. 29 C.F.R. § 1910.919(b) (proposed), 64 Fed. Reg. 66071. By contrast, DLI's Rule dictates that employers "must reduce all WMSD hazards below the criteria" established in mathematical formulas incorporated into the Rule, with no option for "incremental" abatement. WAC 296-62-05130(4). The projected costs of implementing controls for the less demanding federal standard, therefore, are necessarily less than the costs required to implement DLI's Rule.

Moreover, DLI did not even take the time to fully understand the PEA prior to relying almost exclusively upon it for this calculation. For example, in the CBA, DLI claims that "170 workplace scenarios" developed by ergonomists were "[t]he basic information used to estimate engineering and administrative control costs" in the PEA. CBA, AR 118043. This simply is not true. OSHA decided the scenarios were

inaccurate and discarded them in favor of a process in which three ergonomists developed direct estimates of "average costs of job interventions for each occupational group." PEA, CP 105. DLI was also wrong when it stated that OSHA "used its own ergonomic employer survey to estimate the number of workers in each occupational grouping at the three digit SIC level." CBA, AR 118043. Although OSHA used its survey and two other sources to define occupational groups, the actual number estimates were taken from National Industrial Staffing Patterns, a Bureau of Labor Statistics publication. See PEA, CP 106.

Even if the PEA had reflected Washington's Rule rather than the federal rule, and even if DLI had understood the methods employed by OSHA, the PEA is nonetheless a faulty measure of control costs. This is because the three ergonomists who were asked to "estimate the average costs of job interventions defined by OSHA" were given no guidance as to the type of controls to be considered. PEA, CP 105. Nor were they aware of the standards to be complied with, as OSHA had yet to formulate the proposed federal rule at that time. Instead, the ergonomists were given complete discretion and OSHA relied upon their "professional experience in designing and implementing ergonomic interventions...to develop these cost distributions." Id. The ergonomists developed these cost estimates for occupational groups which OSHA defined by such vague terms as "machine operator," "hand worker," or person engaged in "other" or "miscellaneous" occupations. See PEA, CP 103. These groups were lumped together into 26 broad categories from more than 92 million

covered employees in all industries. See id. Not only are the groupings questionable on their face because of the diversity of work activities and controls encompassed within them, but the cost evaluators, as ergonomists, were not qualified to understand or apply the categories.[8]

Finally, given the ergonomists' obvious self-interest in the promulgation of a rule which will result in a vast increase in the demand for their services, a reasonable person could not rely on their findings as sufficiently detached to qualify as of an "expert" nature. See ACLU v. Blaine Sch. Dist. No. 503, 95 Wn. App. 106, 119-20, 975 P.2d 536, 543 (1999).

For all of these reasons, DLI's cost estimate is unreliable and fails to "persuade a reasonable person." RCW 34.05.328(2). The Rule should be overturned.

**2. Benefits were overstated and equally unpersuasive.**

To arrive at its estimate of the Rule's asserted benefits, DLI first estimated the number of WMSDs it believed were likely to occur absent regulation, then took into account the likely effectiveness of the Rule, and finally assigned a monetary value to the number of WMSDs likely to be prevented as a result of the Rule. See CBA, AR 118059. The three data

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[8] The qualifications of the ergonomists whose work formed the basis for the PEA was one of the subjects excluded by the court below. See Part V(G), below. Clearly, the qualifications of a claimed expert are relevant to consideration of the value to be given that expert's opinion. By not including this information in the official rule-making file, DLI has unfairly bolstered its record. For the reasons explained in Part V(G), the Superior Court erred.

sources relied upon by DLI for this benefit calculation are unreliable and, as demonstrated below, resulted in greatly overstated benefits.

**a) DLI's reliance on worker's compensation data was faulty.**

DLI used worker's compensation data from 1995 through 1997 to project the number of WMSD injuries likely to occur annually. See CBA, AR 118059. Although the analysis refers to "WMSD claims" as if that were a defined and measurable term under Washington's workers compensation system, it is not. The injury estimates used in the analysis were manufactured through a complex aggregation of "body part," "nature," and "type" code data. See B. Silverstein & J. Kalat, Work Related Disorders of the Back and Upper Extremity in Washington State, 1990-1997 (hereinafter "Work Related Disorders"), App. 2, Exh. G, H (AR 104033, 104043). Judgments had to be made by DLI as to which of these codes were likely to correspond with the Rule's vague WMSD definition. See id.

When OSHA engaged in a similar exercise at the federal level, the national statistics it generated were roundly criticized as overinclusive. See 64 Fed. Reg. 65931-32. DLI's analysis is even worse, including codes that OSHA properly excluded such as "rubbed or abraded" and "objects being handled (not vibrating)." Compare 64 Fed. Reg. 65931-32 with Work Related Disorders, AR 104043. Other examples of inappropriate codes counted by DLI include "bodily reaction" and even "unknown" incidents. See AR 114226. None of the additional codes have any

apparent connection to the WAC 296-62-05150 definition of WMSDs; yet they add significantly to the total injury number asserted in DLI's cost-benefit analysis.

Additionally, the workers compensation data relied upon by DLI was not automatically segregated into "gradual onset" and "sudden onset" claims. Because the Rule purports to regulate "gradual onset" incidents only, DLI had to separate out "sudden onset" claims after deriving a total number of alleged WMSDs through the coding process. See WAC 296-62-05150 ("For purposes of this rule WMSDs do not include injuries from slips, trips, falls, motor vehicle accidents or being struck by or caught in objects."); see also CES, AR 117643 (describing WMSDs as "non-traumatic soft tissue musculoskeletal disorders"). DLI allegedly did this using information from the claims database. See Work Related Disorders, AR 104043. However, to have arrived at its published total of 68,146 annual reported WMSD claims, DLI had to have counted all the workers compensation data, including "sudden onset" claims. See Work Related Disorders, AR 104058.[9] In fact, amputations, contusions, fractures, injuries in which employees were struck by objects, falls and even

[9] Of approximately 60,000 average annual claims filed from 1990 through 1997, only about half (approximately 31,000) were classified by the authors as "gradual onset" with the remainder being "sudden onset." AR 104058. Annual breakdowns were not provided for the 1995-97 data subset extracted by DLI to achieve its even higher figure of 68,146, but the larger data set makes clear that both "gradual onset" and "sudden onset" were included.

automobile accidents were improperly counted as includable "sudden onset" incidents. See AR 104055.

When presented with this argument below, DLI's only response was that it actually used "a more timely and complete 2000 report." Significantly, however, the 2000 report is not included in the CBA's reference list, CBA, AR 118091-102, and it is cited only once for a completely separate point. See CBA, AR118064.[10] While DLI has never provided a coherent reconciliation of the alleged 1999 and 2000 numbers, the point is moot because there is nothing in the record to show that DLI even relied on the later data, much less allowed the public to comment on it.

Although the State of Washington accounts for just over 2% of the nation's workforce, DLI's reported lost time WMSD estimate is 3.64% of the nationwide number estimated by OSHA. Compare CBA, AR 118062 (23,456 WMSD claims involving lost-time) with 64 Fed. Reg. 65931 (647,344 national lost-time MSDs in 1996). DLI's estimate, therefore, is nearly twice as high as the national number that even OSHA conceded was too large.[11] Nonetheless, DLI claims an ability to reduce these

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[10] The CBA further explains that DLI's analysis was derived from "data on WMSDs for the years 1995-1997." CBA, AR 118059. "Data for 1998"—the year that was added to the 2000 report—"was not used because the full cost of these claims is not yet fully captured in the databases we used to calculate costs of claims." Id.

[11] Washington's share of the 647,344 MSDs recorded nationally in 1996 would be approximately 13,000—not the 23,456 DLI claims to be addressing in its Rule. OSHA, moreover, has conceded that this national MSD count, which has declined substantially since 1996, includes a substantial number of incidents "result[ing] from

(continued...)

inflated injury numbers by forty percent, and resulting costs by 50 percent, as discussed below, see CBA, AR 118077, through a Rule that does not even apply to many of the claims being counted. Thus, its benefit claims, at best, are inflated by many multiples.

**b) DLI's "Success Stories" are skewed and an inadequate basis for estimating costs.**

Once DLI decided upon an estimate of the number of WMSD injuries likely to occur, it then assessed the Rule's alleged effectiveness in reducing that number. In making such assessment, DLI relied on "63 reports and publications on the success of ergonomics programs in a wide range of work environments." CBA, AR 118073. Notwithstanding DLI's misleading description, these "publications" are not "studies" in any legitimate scientific sense. Indeed, DLI later admitted that it did not view these reports as "scientifically validated information." See CP 586. They are more accurately portrayed by the term repeatedly used in DLI's notes: "sucess [sic] stories." WC 0468080-81; 046094. These success stories had no way of filtering out biases or other influences. The compilation is substantially made up of raw observations – "stories" from non-scientific personnel such as government accountants ("GAO 1997"), industrial engineers (e.g., "Garg, 1997"), occupational therapists ("Tadano, 1990"),

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short-term rather than chronic exposures," which would not be addressed under the Washington Rule. 65 Fed. Reg. 68271.

union safety and health advocates (e.g., "Narayan, et al., 1993") and corporate officials. See CBA, AR 118125-27. In many cases, the source is the very person in charge of the ergonomics program being described, who naturally desires to cast personal achievements in the most favorable light. See, e.g., id. ("Jones, 1997").

Moreover, DLI apparently made no attempt to determine whether the 63 "success stories" were representative of actual experience, even though DLI itself recognized an inherent reporting bias which manifests in greater self-reporting of successes than failures.[12] See WC 046094, DLI Working Notes (describing need to "compensate for reporting of sucess [sic] stories."). It simply is not credible for DLI to assert that every ergonomics program is a stunning success based on a handful of anecdotes. If that were true, and more than half of all employees already work in establishments with ergonomics programs, PEA at 10 (CP 507-512), then the WMSD numbers should already have decreased far more dramatically than they have. Compare CES, AR 117656-658 (DLI

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[12] Often, this bias manifests itself in blatant attempts to recast unfavorable results to make them appear favorable, such as a NIOSH report falsely characterized a general upward trend in MSDs as a 55% decrease by drawing comparisons to an aberrational year at least two years prior to the implementation of an ergonomics program. See J. McGlothlin & S. Baron, NIOSH Investigation No. HETA 91-208, May 1994, at Table 8, CP 193-219; see also D. Ridyard, "A Successful Applied Ergonomics Program for Preventing Occupational Back Injuries," in Advances in Industrial Ergonomics and Safety II 125, 132 (1990), CP 228-232 (attributing 62% decrease to an ergonomics program when the entire decrease took place before the program's implementation and rates had increased since then). Such problems render the so-called "studies" useless for any kind of serious analysis.

assertion that WMSDs numbers remain high and that the recent decline has not been significant).

Finally, none of the "success stories" purport to assess the measures mandated by DLI's Rule. Indeed, many of the subject measures conflict with the Rule. See, e.g., J. Melhorn, et al., "An Outcomes Study of an Occupational Intervention Program for the Reduction of Musculoskeletal Disorders and Cumulative Trauma Disorders in the Workplace," JOEM, 41:833-846 (1999), App. 2, Exh. EEE, CP 507-512 (assessing CtdMAP™ approach that does not implement a single job control as contemplated by the Rule, but instead screens out potential workers based on survey data); T. Holland, "Injury Rates Plummet with Behavior-Management Program," Safety & Health, Nov. 1991, at 50, CP 182 (trade publication article by non-scientist claiming that efforts to address "[b]ehavior and attitude" can have a marked effect on injury rates).

For all of these reasons, DLI's reliance on the various "success stories" discussed above to evaluate the effectiveness of the Rule was inappropriate.

**c) DLI's reliance on epidemiological literature is misplaced.**

DLI also relied upon a review of "risk ratios" gleaned from "epidemiological literature" to assess the Rule's effectiveness. See CBA, AR 118073. This analysis assumed that removal of the "risk" attributed to a factor automatically reduces the injury rate statistically associated with

that risk. See, e.g., CBA, AR 118074-77. Such a simplistic analysis is unrealistic, especially in the ambiguous field of ergonomics. Even DLI concedes that a myriad of factors such as non-work activities, age, gender, other diseases, and anatomic differences contribute to MSDs. See CES, AR 117658. It is also widely recognized that psychosocial variables play a major role and none of the epidemiological studies cited by DLI control for these other variables, nor could they for the reasons discussed infra.

In analyzing the epidemiologic results, moreover, DLI relied exclusively on estimates of "relative risk"—the comparison of "risk" for persons exposed to a particular condition and persons not exposed. See CES, AR 117737; see also id. CES, AR 117704 at n.43 (DLI definition of "relative risk). The problem, however, is that this ratio never takes any account of the amount of "risk" that existed in the first place. A "risk ratio" of 2.0, for example, might mean that 100% of a population develops a "disorder" under certain conditions but only 50% have that "disorder" if the condition is removed; but it could just as easily mean that the risk is 0.0002% under certain conditions and 0.0001% if that condition is removed. See id. The "absolute risk," defined as "the proportion of patients who are spared the adverse outcome by taking the therapy," Guyatt G. & Rennie D., Users' Guide to the Medical Literature: Essentials of Evidence-Based Clinical Practice, 2002:269-80 (AMA Press), would be 50% in the first example but only 0.0001% in the second. DLI is erroneously treating "relative risk" as if it were "absolute risk," which is the only relevant question for purposes of its benefit analysis.

Even worse, it is using "relative risk" from studies examining only a small, discrete portion of the suspected "WMSD" problem—which may individually represent only a limited background risk—as a basis for extrapolating "absolute risk" reductions for every WMSD encompassed in the Rule.

Thus, epidemiological evidence is insufficient to assess the outcome of interventions such as the Ergonomics Rule. If it were sufficient, then the entire clinical trial process required by the Food and Drug Administration could be abolished because the effectiveness of medications could be determined merely from risk ratios associated with disease. There are good reasons why epidemiological evidence is not used in this fashion, and the same reasons apply to DLI's assessment of benefits in this case. Like the "success stories" relied upon by DLI, the epidemiological literature does not specifically analyze the Rule at issue here. Even DLI acknowledged that it is "[d]ifficult to compare [the studies] to caution zone, hazard zone limits." CP 148 (DLI's Working Notes).

Accordingly, like DLI's estimate of costs, the estimate of benefits is misleading and the evidence cannot convince a reasonable person that the amount is justified.

**3. Other flaws in DLI's analysis warrant overturning the Rule.**

In addition to DLI's use of underestimated costs and exaggerated benefits, other flaws in its cost-benefit analysis mandate the Rule be

overturned. For example, it is indisputable that the "best available evidence" for calculating costs is the actual price of controls that have been demanded during prior ergonomics enforcement activities. Although at least one such estimate was submitted during the public comment period, DLI chose not to consider, much less rely upon it. See AR 206480, 206496 n.76, App. 2 Exh. XX, YY M. Cubed's Analysis (summarizing costs in the trucking industry). Nor did DLI produce or seek out other data like it. Choosing instead to use the inferior evidence discussed in detail above, DLI purposefully manipulated the results of its analysis.

In estimating the scope of coverage under its Rule, moreover, DLI's own working notes indicate that the Department was proceeding in "total ignorance" as to the overlap of covered risk factors. WC 046147 (App. 2, Exh. PPP). These notes further state that DLI took credit for reductions on account of these overlaps based on "sheer speculation." Id. DLI's only defense of these notes is to say that the author, Mr. Michael Foley, was not a policy-maker. See RP 137:22-38:10. Even if that were true, it is no excuse, for this is a data question and not a policy decision. Mr. Foley was the person responsible for crafting and writing the analysis, and he was in the best position to know how the Department was proceeding. Proceeding in "total ignorance" is not a justifiable basis for a cost-benefit analysis by any reasonable person's standards.

Although not factored into the cost-benefit calculation, DLI repeatedly stresses and plays up certain social benefits of the Rule which it

claims are not quantifiable. For example, DLI cites benefits that it claims will occur as a result of reduced injuries, including less pain and suffering by workers, less interference with family life, and reduced household economic costs. See CBA, AR 118079-80. However, all of these alleged benefits depend upon the premise that the Rule will actually prevent injuries—a premise which is anything but clear. See infra at Part V(D)(2). Moreover, DLI does not similarly acknowledge the qualitative costs of the Rule to employers and employees alike. For example, as the only state to require broad-ranging, quantified ergonomics compliance regardless of the existence of WMSDs, Washington will certainly lose business opportunities it might have otherwise retained or even gained. Employees will ultimately suffer because of lost jobs and a further weakened economy. A state that is already near the top of nationwide unemployment statistics, and that currently leads the nation in lost jobs per month, cannot afford this burden. See Bureau of Labor Statistics news release, Oct. 22, 2002 (http://www.bls.gov/news.release/laus.nr0.htm) ("Washington recorded the largest percentage decline in employment (-2.1 percent)" in the most recent monthly unemployment statistics).

The errors in DLI's analysis are more than sufficient to overwhelm the "margin of error" perceived by the court below. CP 2180 (Order). By itself, removal of the "total ignorance" reduction described above would have nearly tripled estimated costs if DLI had simply applied OSHA's more neutral compilation of the very same survey results. See CP 526 (contrasting DLI's assertion that only 12% of jobs would constitute

"hazards" under the Rule with OSHA's compilation of the very same Washington survey results, which report the corresponding percentages as 33%). DLI further estimated the cost of engineering and administrative controls at only $25.11 per employee, AR 117659, when a realistic and unbiased assessment would have acknowledged potential equipment costs running many times that level. Compare AR 206480, 206496 n.76, (App. 2, Exh. XX, YY) (trucking industry analysis). On the benefits side, moreover, at least 40% of the "injuries" that DLI takes credit for reducing are not even covered by the Rule. See supra at fn 10. And that does not even consider the problems with DLI's wildly optimistic projections of success, its misuse of epidemiologic evidence, the low participation and poor design of its survey, the lack of correlation between that survey and the Rule, and the countless other shortcomings in DLI's analysis.

Therefore, despite its length, the Department's cost-benefit analysis is unreasonably lacking in quality and substance. As the Court in Aviation West noted at the outset, "[t]he size of the record in this case, which fills 15 boxes, is quite irrelevant to the question of whether the Department fulfilled its statutory obligation." 138 Wn.2d at 418. The same is true here. The Court must look past this artificial display and find that no reasonable person would be convinced by the evidence that DLI's cost-benefit calculation was justified. The Rule must be overturned.

**D. The Ergonomics Rule exceeds the Department's Authority, is Not Based on the Best Available Evidence and is Not Needed.**

RCW 49.17.050(4) governs the scope of DLI's authority to enact safety and health rules and regulations:

> In the adoption of rules and regulations under the authority of [RCW Chapter 49], the director shall:
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> * * *
>
> (4) provide for the promulgation of health and safety standards and the control of conditions in all work places concerning gases, vapors, dust, or other airborne particles, toxic materials, or harmful physical agents. . . .

It is fundamental that any such rules and regulations be based on "the best available evidence." RCW 49.17.050(4); see also Aviation West Corp. v. Washington State Dep't of Labor & Indus., 138 Wn.2d 413, 425, 980 P.2d 701, 707 (1999). The "best available evidence" does not mean the most voluminous evidence, and the best available evidence requirement cannot be circumvented by the Department's policy preferences or financial constraints. See Rios, 145 Wn.2d at 505-08 (decision to not regulate known pesticide hazard was arbitrary based on Department's rationale of "limited resources"). Most importantly, because the Rule is a significant legislative rule, the RRA requires that DLI have determined that the Rule is "needed" to achieve the general goals and specific objectives of the statute that the Rule implements, RCW 49.17. RCW 34.05.328(1)(b). The Department acknowledged that the RRA requires that this determination of need be justified by evidence of a sufficient quantity and

quality so as to persuade a reasonable person. RCW 34.05.328(2); See RP at 23:19-24:1.

This Court is not being asked to "await the Godot of scientific certainty" instead of relying on the best evidence currently available. United Steelworkers of America v. Marshall, 647 F.2d 1189, 1266 (D.C. Cir. 1980). It need not wait because the best evidence is available now, and it undermines DLI's position. DLI has selectively cited epidemiological evidence that assertedly supports the need to regulate, but it has ignored the results of randomized controlled trials, an indisputably superior form of scientific evidence. See infra. at Part V(D)(b).

In fact, the same type of evidence cited by DLI to justify this major public policy initiative has been repeatedly rejected, even as a basis for routine tort claims, under the "junk science" standard of Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d. 469 (1993). These courts have found, among other things, that "'ergonomic risk factors' ... are, by their very nature, matters not reducible to scientific certainty and any attempt to pretend otherwise is calculated to confuse and mislead the jury." Pretter v. Metro North R.R., 206 F. Supp. 2d 601, 603 (S.D.N.Y. 2002). For these reasons and others discussed further below, DLI exceeded its statutory authority in promulgating the Ergonomics Rule and failed to justify the need for the rule with either the best available evidence or evidence sufficient to persuade a reasonable person.

### 1. DLI Exceeded its Authority under WISHA and Common Sense in Attempting to Regulate Simple Physical Activity in the Workplace.

The Ergonomics Rule identifies fourteen different physical "risk factors," various positions, movements and physical activities, that at specified levels are assumed by the Department to comprise "WMSD hazards" associated with the occurrence of WMSDs. See WAC 296-62-05105, -05130. DLI's position is that employees' physical activities falling within the criteria for "WMSD hazards" are "harmful physical agents" and thus subject to its rulemaking authority under RCW 49.17.050(4). See RP at 88:21-88:5 (conceding that the Ergonomics Rule rested on RCW 49.17.050(4)).

However, DLI can offer no authority that the simple physical movements, such as the bending one's back, neck or wrist or the lifting of various weights which it seeks to regulate through its Rule, are "harmful physical agents" within the meaning of RCW 49.17.050(4). Indeed, reviewing the term within the listing of other conditions covered in RCW 49.17.050(4) shows that all such conditions are *external* hazards in the workplace which impact an employee's safety or health, not the employee's own physical movements.

RCW 49.17.050(4) has been held to authorize the regulation of external hazards such as pesticides, second hand smoke, and noise. See, e.g., Aviation West Corp. v. Washington State Dep't of Labor & Industries, 138 Wn.2d 413, 980 P.2d 701 (1999) (regulation of environmental tobacco smoke in workplaces); Rios 145 Wn.2d 483 (in an

under-regulation case, regulation held warranted regarding employee exposure to pesticide with known deleterious effects on the nervous system); WAC 296-62-09015 (WISHA's hearing conservation standard). The Ergonomics Rule goes far beyond the permissible regulation of "harmful physical agents" by attempting to dictate the physical movements of employees, and exceeds the scope of the Department's authority set forth in RCW 49.17.050(4).

Moreover, DLI's position that the physical activities regulated by the Rule are "harmful" is belied by DLI's own practice to use "work hardening" programs in the administration of its industrial insurance programs. See WAC 296-23-225, -223. Such programs are specifically designed to use real or simulated work tasks and conditioning exercises to increase injured workers' strength and endurance and facilitate a return to work. See DLI Provider Bulletin, No. 90-06, p. 1. Unlike exposures to pesticides, environmental tobacco smoke or excessive occupational noise, exposure to physical activity in and of itself has not been established as a "harmful" physical agent and DLI was without authority to promulgate a rule regulating such activity under RCW 49.17.050(4).[13]

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[13] To the extent the Superior Court determined that an examination under RCW 49.17.050(4) was unnecessary to address the issue of DLI's authority to promulgate the Ergonomics Rule, the court erred. RCW 49.17.050(4) is clearly the statutory rulemaking provision against which DLI's purported authority to promulgate its Ergonomics Rule must be measured. See, e.g., Aviation West Corp. v. Washington State Dep't of Labor & Indus., 138 Wn.2d 413, 425, 980 P.2d 701 (1999) (in workplace smoke regulation case, stating the Department's authority to issue rule must be based "the best available evidence" pursuant to RCW 49.17.050(4)); Rios v. Washington Dep't of Labor & Indus.,

(continued...)

### 2. DLI Failed to Rely on the "Best Available Evidence" in Enacting its Rule.

As noted above, any rule or regulation adopted pursuant to the WISHA must be based on the "best available evidence." RCW 49.17.050(4). Appellants do not seek invalidation of the Rule because the rulemaking record contains conflicting evidence. Rather, the Rule should be invalidated because of the fundamental unreliability of the medical evidence on which the Rule is based and on the availability of superior evidence that undermines the Rule. The evidence cited by DLI would not persuade a reasonable person that the Rule is needed; DLI ignored the best available evidence in the record, which would not support the Rule. This coercive regulation thus does not meet the "best available evidence" standard required for safety and health regulations by RCW 49.17.050(4).

#### a) Reliance on Epidemiological Studies, By Themselves, Is Insufficient.

In enacting the Ergonomics Rule, DLI relied almost exclusively on epidemiological studies, which evaluate the statistical associations between exposure and outcome. The Department recognized that it relied on the accumulation of epidemiological studies supporting a supposed, but admittedly tenuous, correlation between work activities and MSDs, piecing together its analysis from a large body of admittedly flawed

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145 Wn.2d 483, 494, 39 P.3d 961 (2002) (in an under regulation case involving pesticide exposure issues, citing RCW 49.17.050(4) as "the WISHA provision regarding safety and health standards for exposure to toxic agents").

materials. CES, AR 117634, 117638-7639. DLI justified its approach by relying upon Public Citizen Health Research Group v. Tyson, 796 F.2d 1479 (D.C. Cir. 1986); however, the glaring shortcomings of the epidemiological evidence itself and the reasoning of Public Citizen undermine the Department's professed scientific support for its Rule.

First, epidemiological studies are recognized as only "a first step in assessing the work-relatedness of MSDs," and before cause and effect conclusions are drawn, such studies should be followed up with other forms of scientific research. NIOSH Musculoskeletal Disorders and Workplace Factors: A Critical Review of Epidemiological Evidence, etc., July, 1997, at 1-14, CP 233. "[N]o matter how strong and convincing the association between exposure and outcome, [a] conclusion about cause and effect is not certain." CES, AR 117638. Particularly when more rigorous follow-up studies have actually been conducted, as has occurred here, the Department cannot rely solely on epidemiological studies to conclude there is a causal connection between selected "risk factors" and WMSDs.

The very case upon which DLI relied, Public Citizen, confirms this point.[14] In Public Citizen, the court found that OSHA's attempt to

[14] As noted in Rios, this Court may look to "federal cases interpreting the mirror image OSHA provisions." Rios, 145 Wn.2d at 497, 39 P.3d at 968. Federal safety and health regulations concerning toxic materials or harmful physical agents, such as the one at issue in Public Citizen are authorized pursuant to 29 U.S.C. § 655(b)(5), "the OSHA precursor to RCW 49.17.050(4)." Rios, 145 Wn.2d at 497, 39 P.3d at 968.

establish the carcinogenic effects of ethylene oxide through epidemiological studies alone was insufficient without corroboration from clinically-based "experimental evidence" and "dose-response" evidence to support the exposure limit set by OSHA's regulation. Public Citizen, 796 F.2d at 1487-88. In attempting to regulate the Rule's selected workplace "risk factors," by contrast, experimental randomized controlled trials ("RCTs") fail to corroborate the epidemiologic evidence. Indeed, as noted below, these RCTs contravene the studies relied upon by DLI. See infra.

Washington law similarly does not support an exclusive reliance on epidemiological evidence as "the best available evidence." In Aviation West, the "best available evidence" on the effects of secondhand smoke, the substance to be regulated, was an EPA report where a combination of studies, of which epidemiological studies constituted only a part, were used and weighed according to the EPA's own guidelines for assessing carcinogenic risk. See EPA, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders at 1-2 (Dec. 1992) (cited in Aviation West, 138 Wn.2d at 426, 980 P.2d at 708). In Rios, the Department had decided not to enact a mandatory monitoring program for a particular toxic substance, although its own experts had found such a program both needed and feasible. Rios, 145 Wn.2d at 506-08, 39 P.3d at 973-74. Unlike the present matter and the Aviation West case, however, in Rios the quality of the medical evidence supporting the parties' respective positions was not truly at issue – DLI "did little to parry the

thrust of the TAG report" asserted by petitioners in Rios to be the "best available evidence." Id., 145 Wn.2d at 506, 39 P.3d at 973.

DLI itself recently argued against the use of epidemiological data to quantify causal relationships in the context of evaluating injured workers' claims for permanent disability benefits on occupational hearing loss claims. In Boeing Co. v. Heidy, 147 Wn.2d 78, 51 P.3d 793 (2002), this Court held that statistical studies based on epidemiological data which illustrate tendencies in a particular population were not helpful to triers of fact in determining the actual extent of a worker's work-related disease or disability. Id. at 798. Consistent with Heidy, it is inappropriate for the Department to justify its Rule, which is premised on a causal relationship, by relying only on epidemiological evidence that merely correlates the frequency and distribution of WMSDs, rather than on evidence that tests the existence of a cause and effect relationship.

**b) Randomized Controlled Trials Are the Best Available Evidence – And Those in the Record Do Not Support the Rule.**

The Department's reliance on epidemiological studies is further undermined because the best scientific evidence available regarding the relationship between work-related physical activities and MSDs are prospective randomized controlled trials ("RCTs"). The Department does not dispute such studies are available; it merely asserts, without citation or reasoning, that epidemiological studies are "preferred." AR 117638. However, prospective RCTs are the accepted methodology for testing the effectiveness of health interventions, such as new drugs to be approved by

the FDA. See, e.g., 21 U.S.C. § 355(b)(4)(B) (specifications on the design and since the clinical trials that form "the primary basis of an effectiveness claim" for any new drug); AR 206058 ("The gold standard for evaluating the efficacy of interventions in medicine is the prospective randomized controlled trial (RCT). This is a widely accepted standard across medicine, and across science.").

The only prospective RCTs in the rulemaking record contradict the very assumptions underlying the Ergonomics Rule. One prospective RCT of municipal employees, for example, established that the continuation of ordinary activity promotes more rapid recovery from acute low back pain than bed rest. A. Malmivaara, et al., "The Treatment of Acute Low Back Pain – Bed Rest, Exercises [Passive Stretching] or Ordinary Activity?" 332 N. Engl. J. Med. 351 (1995), CP 187-191 (App. 2, Exh. CCC). Likewise, a prospective RCT involving hospital employees demonstrated that employees who exercised during the week experienced a statistically significant reduction in back pain relative to employees who did not, another example of how physical activity is healthful, not harmful. B. Gundewall, et al., "Primary Prevention of Back Symptoms and Absence from Work: A prospective Randomized Study Among Hospital Employees," 18 Spine 587 (1993), CP 173-180 (App. 2, Exh. AAA). These studies appear to have been arbitrarily rejected, if even considered, by the Department notwithstanding the Department's concession regarding the weaknesses of its epidemiological evidence when it admitted that "no one study conclusively establishes the link between WMSDs and

the[] risk factors [identified in the Rule,] and some studies suggest that such a link does not exist." CES, AR 117639. Although DLI attempts to justify this inadequacy by claiming the Rule is on the "frontiers of science" supported by "inconclusive but suggestive results of numerous studies," id., a large amount of inadequate science does not overcome superior research or satisfy the "best available evidence" requirement of RCW 49.17.050(4).

Indeed, the problem that can arise when regulations are premised on epidemiological evidence is illustrated by two specific ergonomics studies contained in the record. Initially, a retrospective case-control study suggested that preventive education programs (similar to that required by WAC 296-62-05120) might reduce back injury rates among employees at a Boston mail-handling facility. However, this same hypothesis (which is an underlying premise of the Department's own Ergonomics Rule) was later disproved by a prospective RCT conducted by the same group of scientists who posited the initial hypothesis. See CP 166-171 (Daltroy, et al. article).

DLI itself has recognized that, as a regulatory agency, it "must use scientific methods to reach conclusions about cause and effect" to address workplace hazards, such as alleged ergonomic conditions, where the connection between initial exposure and eventual adverse outcome is less apparent. CES, AR 117632. Prospective RCTs, not epidemiological studies, are the best available evidence in reaching the necessary conclusions about cause and effect sufficient to justify regulatory action.

### 3. The Absence of Dose-Response Relationship Evidence Further Undermines the Determination that the Rule is Necessary and Appropriate to Address Workplace Hazards.

DLI does not dispute that MSDs can result from a myriad of factors outside and independent of the workplace, such as age, gender, systemic diseases, anatomic differences and obesity. CES, AR 117658. It also recognizes that "psychosocial factors contribute to the development of WMSDs," citing evidence linking WMSDs with "perceptions of intensified workload, monotonous work, limited job control, low job clarity, and low social support." CES, AR 117655.

DLI contends it has authority to enact its Ergonomics Rule because it "does not attempt to regulate non-work exposures or individual risk factors, [and it] does not claim that compliance with the rule will eliminate" all MSDs among employees. CES, AR 117659. However, WISHA only authorizes the promulgation of health and safety standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," RCW 49.17.020(7). Given that WMSDs are linked, as conceded by the Department, with factors wholly outside the workplace, DLI's failure to offer evidence of a dose-response relationship with work-related "doses" undermines the very premise that the Rule is needed and that a reduction of certain physical activities will correlate with a reduced incidence of WMSDs.

In fact, the Department cannot offer any evidence of a dose-response relationship between the incidence of MSDs and the regulated

even a set of formulas that can reflect what the human body may do in the workplace.

In treating the formulas it has adopted from various sources as a regulatory standard, DLI is using them for a purpose they were never intended to serve. In an article introducing the 1991 NIOSH Lifting Equation noted by DLI, for example, the authors indicated that there was no "scientifically supported, quantitative relationship between the criteria [in the lifting equation] and the actual risk of lifting-related musculoskeletal injury or [low back pain]." T. Waters, et al., "Revised NIOSH Equation for the Design and Evaluation of Manual Lifting Tasks," 36 Ergonomics 749, 752 (1993), CP 267-283 (App. 2, Exh. HHH). The NIOSH index was only intended to serve as a "methodological tool for safety and health practitioners." Id. at 769.

In summary, the medical evidence relied upon by DLI simply fails to establish that the Rule is either necessary or likely to achieve its stated goal of reducing MSDs. The fundamental absence of reliable scientific evidence causally linking the Rule's identified "risk factors" to MSDs likewise undermines the Rule's validity because the Rule is not based on the best available evidence as required by RCW 49.17.050(4). The evidence relied upon by DLI to promulgate its rule, in turn, cannot and does not rise to the level which would persuade a reasonable person that the Rule is needed, and should be invalidated. RCW 34.05.328(1)(b), (2).

**E. DLI Failed to Coordinate the Rule with Other Laws as Required by the APA.**

DLI contends that it met its obligation under RCW 34.05.328(1 to coordinate the Rule "to the maximum extent practicable" with other laws "applicable to the same activity or subject matter" simply by concluding that there were no other such laws. See CES, AR 118001. is wrong for the reasons set forth below. Moreover, DLI is required no only to coordinate its new rule with other federal, state and local laws, RCW 35.05.328(1)(h), but also to justify differences from federal law, sub 1(g), and ensure that the Rule's requirements do not violate other laws, id., sub 1(e).

The only law which DLI recognized might be potentially applicable to the same activity or subject matter was OSHA's then cur regulations on ergonomics. See CES, AR 118000-001. However, bec OSHA had not yet formally promulgated these standards at the time Washington's Rule was adopted, DLI concluded that no federal limita existed and, thus, that it had sufficiently coordinated its Rule. See id. This conclusion is a blatant disregard of the legislature's directive. DI was well aware of OSHA's then current and on-going efforts to promulgate such standards—standards that were as different as "apple and oranges" from its own. See AR 115890. Moreover, the phrase " activity or subject matter" is a broad one and is not limited to laws de with the exact same activity or subject.

## F. The Rule is Unconstitutionally Vague

In addition to being scientifically unsupported, the Rule is unconstitutional because "it is so vague and standardless that it leaves the public uncertain as to the conduct it prohibits," leaving regulators "free to decide, without any legally fixed standards, what is prohibited and what is not in each particular case." Giaccio v. Pennsylvania, 382 U.S. 399, 402-403, 86 S. Ct. 518, 15 L. Ed. 2d 447 (1966); see also Burien Bark Supply v. King County, 106 Wn.2d 868, 871 (1986) ("An ordinance is unconstitutional when it forbids conduct in terms so vague that persons of common intelligence must guess at its meaning and differ as to its application."). This deficiency is especially offensive to due process in light of the fact that violations of the Rule can result in civil fines and criminal sanctions. See RCW 49.17.180, RCW 49.17.190 (2002); Lanzetta v. New Jersey, 306 U.S. 451, 453, 59 S. Ct. 618, 83 L. Ed. 2d 888 (1939) ("No one may be required at peril of life, liberty or property to speculate as to the meaning of penal statutes.").

During the proceedings below, DLI brazenly admitted the "lack of a consistent definition" for the very condition it is regulating: WMSDs. [DLI BRIEF below] at 31 n.30. Its only defense was that this deficiency "is simply no reason to ignore" the issue. DLI, however, has a responsibility to provide a coherent and workable definition. Yet, by recklessly proceeding without deciding what it means to regulate "workplace hazards that can cause or aggravate [WMSDs]," WAC 296-

62-05101, DLI robbed the Rule of the very foundation on which every other substantive requirement must rest.[18]

The Rule, moreover, directs employers who want to escape draconian Appendix B "hazard" thresholds to follow another methodology that is "at least as effective" as various inconsistent calculation tools. WAC 296-62-05130. When the vagueness of this provision was raised during the comment period, DLI offered only the unhelpful aphorism that "[s]cientific bases are needed to assure the validity and reliability of a selected method." CES, AR 117854. This lack of clarity undermines the core of the Rule, which DLI estimates to account for two-thirds of the Rule's total cost. CBA, AR 118056. Its impact has been underscored in a series of "safe harbor" letters issued by DLI,[19] which assure specific employers that they can comply through measures that on their face fall well short of Appendix B thresholds. See, e.g., CP 308-311 (January 7, 2002 DLI Letter to Wal-Mart.[20] For these employers and others who find

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[18] How, for example, can an employer possibly determine when "a physical risk factor . . . has a sufficient level of intensity, duration or frequency to cause a substantial risk of WMSDs, WAC 296-62-05130(1), when DLI has not even decided what a WMSD is? How, moreover, can DLI rationally assess the reliability of research purporting to assess WMSDs or their causes when the studies admittedly suffer from a "lack of a consistent definition." CP 597.

[19] Although this correspondence was excluded by the court below, it clearly relates to the validity of DLI's action at the time it was taken and is needed to determine disputed issues regarding the "unlawfulness of the procedure or of the decision-making process." RCW 34.05.562(1)(b); see infra Part V(G).

[20] The letter, for example, allows employees who work above the head and shoulders merely to vary the height from which orders are picked, when Appendix B clearly would require them to limit such activity to four hours per day. Compare CP 308-311 with WAC 296-62-05174.

the objective Appendix B standards virtually impossible to achieve. DLI is effectively making up the rules at it goes along, in clear violation of constitutional guarantees.

### G. The Superior Court Improperly Denied the Admission of Additional Evidence Which Relates to the Validity of DLI's Action At the Time it Was Taken.

The APA expressly provides for the admission of additional evidence to supplement the record on review in certain circumstances. More than one of those circumstances exists here.

First, WE CARE is specifically challenging the lawfulness of the procedure and decision-making process used by DLI in promulgating the Ergonomics Rule—one of the bases identified by the statute as a reason to supplement the record. See RCW 34.05.562(1)(b) ("[u]nlawfulness of procedure or of decision-making process"). Where that was the circumstance in another case, this Court recognized "in fact, the APA specifically provides that the trial court is permitted to take additional evidence." Aviation West, 138 Wn.2d at 419 (emphasis in original). Moreover, in a rulemaking, the official rulemaking file "need not be the exclusive basis for the agency action on the rule." RCW 34.05.370(4). This is a separate basis for the admission of additional evidence. See RCW 34.05.562(1)(c) ("[m]aterial facts in rule-making...not required to be determined by agency record.").

The latter subsection, RCW 34.05.562(1)(c), is modeled after section 5-114 of the Model State Administrative Procedure Act ("MSAPA") which provides for the admission of new evidence where

necessary to decide disputed issues regarding "any material fact that was not required by any provision of law to be determined exclusively on an agency record of a type reasonably suitable for judicial review." MSAPA at 5-114(a)(3), 15 ULA 141-143 (2000). In the Comment thereto, the Commissioners on Uniform State Laws explained that "paragraph (a)(3) therefore permits the court to receive new evidence regarding any material issues of fact during the judicial review of rules (see Section 3-112(c))." Id. The Commissioners' reasoning is based on the principle that "the record for judicial review should not be the product of the informal rule-making proceedings, but a record especially made for the purpose." Comment to MSAPA 3-112 (citing Auerbach, "Informal Rule Making: A Proposed Relationship Between Administrative Procedures and Judicial Review," 72 N.W. Univ. L.Rev. 15 at 16-17 (1977)). Indeed, it is the agency alone which determines what to put in the official rule-making file.

Finally, the focus of the time limitation in the statute (ie. "at the time it was taken") is on the validity of the agency's action. The statute does not necessarily time-limit the evidence relevant to that action, as DLI argued below and the Superior Court appeared to mistakenly conclude. See CP 507-512. In fact, Arthur Earl Bonfield, one of the Reporters-Draftsmen of the MSAPA, in addressing the exact same statutory phrase in the MSAPA, explained that "material created or accumulated subsequent to the adoption of a rule will often be relevant to the legality of the rule at the time it was initially adopted, and therefore, may be used to facilitate that determination." A. Bonfield, State Administrative Rule

Making Ch. 9, 572 (1986).[21] According to Bonfield, the statutory limitation does not require that "the exclusive basis for that determination of legality be material, actually discovered or in existence at the time the agency action was taken." Id.

**1. Documents Related to the PEA Are Necessary to Determine the Validity of DLI's Reliance on the PEA at the Time of the Rule's Adoption.**

One of the categories of evidence which WE CARE sought to admit as a supplement to the official record was made up of documents related to OSHA's PEA. DLI admits that it relied almost exclusively on the PEA to calculate the cost of implementation controls for its cost-benefit analysis. See Part V, Section C(1)(b), supra. Although the Superior Court agreed to admit the PEA itself into evidence, the court refused to admit documents related to the PEA. See CP 507-512 (Order). These documents, specifically hearing transcripts and witness statements, illuminate flaws in the PEA's methodology which existed at the time the Rule was adopted. Accordingly, the documents are needed to accurately and fully evaluate the validity of DLI's reliance on the PEA as part of its cost-benefit analysis at the time the Rule was adopted.

DLI did not issue its cost-benefit analysis until it promulgated the Rule. See Part V, Section B, supra. Thus, the public had no notice prior

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[21] Bonfield's treatise has been specifically relied upon by our courts in interpreting our state APA. Hillis v. Dep't of Ecology, 131 Wn.2d 373, 399, 932 P.2d 139, 152 (1997).

to the adoption of the Rule and the close of the public comment period that a material part of DLI's cost-benefit analysis would be based on work done by OSHA in the PEA. Accordingly, no one—other than individuals within DLI working on the Rule—had any reason to review, much less submit to the administrative rule-making panel, information pertaining to the preparation and accuracy of the PEA. In point of fact, such information was publicly available. See CP 360. As DLI now acknowledges, OSHA held several days of hearings examining the PEA on which DLI chose to rely. See CP 354 et seq. (Respondent's Memorandum in Opposition to Motion for Ruling on Admission of Documents) at p.7. The transcripts at issue were readily available on OSHA's website. The fact that DLI chose not to examine or include this evidence in the official record does not diminish its relevancy or preclude its admission.

Exclusion of evidence relating to the PEA shields DLI's cost-benefit methodology from criticism that was in the public domain at the time and that directly bears on the validity of DLI's reliance on it. This is contrary to the APA. See RCW 34.05.562(1).

**2. A Subsequent Study by NAS is Necessary to Determine the Validity of DLI's Rule and Specifically, the Regulation of "Musculoskeletal Disorders."**

Another piece of evidence which WE CARE sought to admit and which the Superior Court denied was a study with additional findings, by the National Academy of Sciences ("NAS"), which had prepared one of the two main studies on which DLI did rely. The study confirms the

difficulty in defining "musculoskeletal disorders" and thus, goes to the validity of DLI's Rule which attempts to regulate such a category of disorders. Although the study post-dates the adoption of the Rule[22], it was well known that this more comprehensive report was being prepared, and it therefore bears upon the validity of the agency's action at the time that action was taken. Accordingly, as Bonfield points out, the evidence may and should supplement the record. See discussion, supra.

### 3. Correspondence from DLI Regarding the Rule's Safe Harbor Provision is Needed to Assess the Validity of DLI's Rule Implementation Plan.

The third category of evidence which was denied admission by the Superior Court consisted of correspondence from DLI to Wal-Mart, a prospective Washington employer, and Washington Food Industries, a representative of existing Washington employers, regarding DLI's interpretation and application of the Rule to specific employees, as well as the Rule's safe harbor provision. These documents demonstrate the insufficiency and inaccuracy of DLI's implementation plan required by RCW 34.05.328(3)(a), as well as the inconsistency of DLI's enforcement and administration procedures under that plan. They also are probative of whether the Rule is so vague and subject to arbitrary interpretations as to

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[22] DLI relied on several predecessor reports from the same agency. See AR 112481 and 112608.

violate Constitutional guarantees. Although the documents post-date the adoption of the Rule, they once again relate to the validity of the agency's action at the time it was taken. See Bonfield discussion, supra.

Based on the foregoing, the Superior Court erred in refusing to supplement the record with the above-identified evidence which is necessary to properly evaluate the validity of DLI's action in adopting the Ergonomics Rule.

## VI. Conclusion

For all of the reasons stated above, the Rule should be deemed void pursuant to RCW 34.05.375 for the agency's failure to comply with statutory rule-making procedures. It has long been Washington law that the proper remedy for failing to comply with the state's APA requirements is invalidation of the regulation. See Failor's Pharmacy, 125 Wn.2d at 497. Moreover, the rule substantively fails the requirements of WISHA. It is not supported by the best available evidence, and certainly the Department's admitted "speculation" as to the Rule's costs and benefits is insufficient. Accordingly, WE CARE respectfully requests that the Court invalidate the Ergonomics Rule, WAC 296-62-051 et seq.

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